REMARKS

The amendments to the claims do not add new matter. Claim 59, which was amended to recite that the implant is sized and shaped for use in "lumbar" spinal fusions, is supported in the specification at page 17, lines 26-27 ("may be implanted, for example, to assist in induction of posterior **lumbar** intervertebral fusion PLIF);" emphasis added in bold. In addition, claim 59 has been amended consistent with the preambular term "elongated," to recite the dimensions of the elongated implant. Support for the recited dimensions are found in the specification at page 17, line 30 to page 18, line 4: ("Preferably, the device as used for PLIF applications has the following dimensions similar to the following, see side view FIG. 8D:a width 811 of approximately 7 to 12 mm, ... See FIG. 8E, rear view: a length L of about 20 to 26 mm; a height H of between about 7.5 and 14.5 mm;. . ."). Consistent with FIG. 8D, claim 59 also reflects that the first side wall and the second side wall of the elongated implant are "outer" side walls.

Claim 69, which is directed to a method of fusing "lumbar" vertebrae, using the implant of claim 59, is supported throughout the specification, including at page 17, lines 26-27 ("may be implanted, for example, to assist in induction of posterior **lumbar** intervertebral fusion PLIF);" emphasis added in bold.

Claim 70, which is directed to a method of fusing "lumbar" vertebrae, is supported throughout the specification, including at page 17, lines 26-27 ("may be implanted, for example, to assist in induction of posterior **lumbar** intervertebral fusion PLIF);" and at page 18, line 27 to page 19, line 2 ("In use, the implant 810 is inserted on either side of lumbar intervertebral spaces to thereby stabilize and assist in fusion of adjacent lumbar vertebrae. This is accomplished by distraction of the **lumbar** vertebrae, removal of an appropriate amount and shape of intervertebral disc matter, and insertion of the implant 810, preferably on each side on a posterior approach, according to methods known in the art. The concave surface of each implant 810 is set to face inwardly, toward the center of the vertebral body, while the convex surface of the implant 810 is set to match, as much as possible, the natural external curvature of the lumbar vertebrae."); emphasis added in bold. Consistent with FIG. 8D, claim 70 also reflects that the first side wall and the second side wall of the elongated implant are "outer" side walls.

New claim 81, which is directed to the implant of claim 59, having an overall width of "about 9.4 mm to about 10 mm" is supported in the specification at page 17, lines 31-32 ("see side view FIG. 8D:a width 811 of approximately 7 to 12 mm, ...and preferably about 9.4 to about 10 mm;").

New claim 82 is directed to an elongated implant having all of the dimensions recited in claim 59 and wherein the second outer side wall comprises a "concave surface." Claim 82 is supported by the same written description as cited for claim 59 and the disclosure in FIG. 8D (showing the concave second outer side wall).

Claim 83, which is directed to the elongated implant of claim 82, wherein the overall width is from "about 9.4 mm to about 10 mm," is supported in the specification at page 17, lines 31-32 ("see side view FIG. 8D:a width 811 of approximately 7 to 12 mm, ...and preferably about 9.4 to about 10 mm;").

Claims 84, 85, 86 and 87, which recite that the height of the elongated implant is "8 mm," 10 mm," "12 mm," and "14 mm," respectively, are supported throughout the specification, including at page 18, lines 4-6 ("See FIG. 8E, rear view: a length L of about 20 to 26 mm; a height H of between about 7.5 and 14.5 mm; preferably, heights of about 8, 10, 12, and 14 mm are produced . . .)."

Claim 88, which is directed to the elongated implant of claim 82, wherein the substantially planar upper surface or substantially planar lower surface is machined so that it has "ridges directed to the posterior end of the implant," is supported throughout the specification, including at page 18, lines 7-9 ("ridges directed to the posterior end 819 of the PLIF implant prevent backing out of the implant. A detail of one embodiment of such a ridged surface is shown in FIG. 8F. . . ."); and at FIGS. 8D and 8F.

Claim 89, which is directed the elongated implant of claim 88 wherein the distances between tooth crests in said ridges is "about 1 to 2 mm," is supported in the specification at page 18, line 11 ("a distance between tooth crests 821 of about 1-2 mm, . . .").

Claim 90, which is directed to the elongated implant of claim 82 wherein said posterior face is machined for "instrument attachment," is supported throughout the specification, including at page 18, lines 16-18 ("an instrument attachment means, 826,

such as a tapped instrument attachment hole, is provided in the posterior face of the PLIF implant; this feature is best seen from the posterior view 8G, ...").

Claim 91, which is directed to the elongated implant of claim 90 wherein said "posterior face has an instrument attachment hole," is supported throughout the specification, including at page 18, lines 17-24 ("this feature is best seen from the posterior view 8G, which shows: **an instrument attachment hole** 826 having a diameter of about 1.5 to about 2.5 mm, preferably about 2 mm, and a depth of about 4-5 mm, preferably about 4.5 mm; an edge to center of the **instrument attachment hole** dimension 827 is carefully defined to match dimensions of any implant insertion device used in combination with this embodiment of the PLIF implant; a center of the **instrument attachment hole** to edge dimension 828 is about 4-6 mm, preferably about 5 mm, with a ridge 829 of about 1 mm running along three edges of the posterior face of the implant."); emphasis added in bold.

Claim 92, which is directed to the elongated implant of claim 91 wherein said instrument attachment hole is a "tapped instrument attachment hole," is supported throughout the specification, including at page 18, lines 16-18 ("an instrument attachment means, 826, such as a tapped instrument attachment hole, is provided in the posterior face of the PLIF implant; this feature is best seen from the posterior view 8G, ...").

Claim 93 is an independent claim directed to an elongated bone implant for use in lumbar spinal fusions. Claim 93 recites the same dimensional limitations as claim 82 but also includes as an element, "said first outer side wall comprises a convex surface that defines an outside angle of between about 60° and 75° with said posterior end, said second outer side wall comprises a concave surface." Support for the angle defined by the convex wall is found in the specification at page 17, line 31 to page 18, line 3 ("see side view FIG. 8D: . . . a curvature that defines an angle 816 of between about 60 and 75 degrees, and preferably about 67 degrees.").

Claim 94, which is directed to the elongated implant of claim 93, wherein the overall width is from "about 9.4 mm to about 10 mm," is supported in the specification at page 17, lines 31-32: ("see side view FIG. 8D:a width 811 of approximately 7 to 12 mm, and preferably about 9.4 to about 10 mm; . . .").

Claims 95, 96, 97 and 98, which recite that the height of the elongated implant is "8 mm," 10 mm," "12 mm," and "14 mm," respectively, are supported throughout the specification, including at page 18, lines 4-6 ("See FIG. 8E, rear view: a length L of about 20 to 26 mm; a height H of between about 7.5 and 14.5 mm; preferably, heights of about 8, 10, 12, and 14 mm are produced . . .)."

Claim 99, which is directed to t he elongated implant of claim 93, wherein said outside angle is "about 67°," is supported in the specification at page 17, line 31 to page 18, line 3 ("see side view FIG. 8D: . . . a curvature that defines an angle 816 of between about 60 and 75 degrees, and preferably **about 67 degrees**."); emphasis added in bold.

Claim 100, which is directed to the elongated implant of claim 93, wherein the substantially planar upper surface or substantially planar lower surface is machined so that it has "ridges directed to the posterior end of the implant," is supported throughout the specification, including at page 18, lines 7-9 ("ridges directed to the posterior end 819 of the PLIF implant prevent backing out of the implant. A detail of one embodiment of such a ridged surface is shown in FIG. 8F. . . ."); and at FIGS. 8D and 8F.

Claim 101, which is directed the elongated implant of claim 100 wherein the distances between tooth crests in said ridges is "about 1 to 2 mm," is supported in the specification at page 18, line 11 ("a distance between tooth crests 821 of about 1-2 mm, . . .").

Claim 102, which is directed to the elongated implant of claim 93 wherein said posterior face is machined for "instrument attachment," is supported throughout the specification, including at page 18, lines 16-18 ("an instrument attachment means, 826, such as a tapped instrument attachment hole, is provided in the posterior face of the PLIF implant; this feature is best seen from the posterior view 8G, ...").

Claim 103, which is directed to the elongated implant of claim 102 wherein said "posterior face has an instrument attachment hole," is supported throughout the specification, including at page 18, lines 17-24 ("this feature is best seen from the posterior view 8G, which shows: **an instrument attachment hole** 826 having a diameter of about 1.5 to about 2.5 mm, preferably about 2 mm, and a depth of about 4-5 mm, preferably about 4.5 mm; an edge to center of the **instrument attachment hole** dimension 827 is

carefully defined to match dimensions of any implant insertion device used in combination with this embodiment of the PLIF implant; a center of the **instrument attachment hole** to edge dimension 828 is about 4-6 mm, preferably about 5 mm, with a ridge 829 of about 1 mm running along three edges of the posterior face of the implant."); emphasis added in bold.

Claim 104, which is directed to the elongated implant of claim 103 wherein said instrument attachment hole is a "tapped instrument attachment hole," is supported throughout the specification, including at page 18, lines 16-18 ("an instrument attachment means, 826, such as a tapped instrument attachment hole, is provided in the posterior face of the PLIF implant; this feature is best seen from the posterior view 8G, ...").

Claim 105 is an independent claim that recites all of the elements of claim 93 and the further element that the elongated implant is "crescent shaped." Support for the recitation of "crescent shaped" is found in FIG 8D which shows the top view of the crescent shaped implant 810.

For all these reasons, the amendments to the claims are fully supported by the specification as originally filed.

Bases for Rejection

Claims 59-61, 65-66 and 70-71 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,728,159 (Stroever).

Claims 59-61, 65-66 and 70-71 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,371,988 (Pafford).

Claims 59-61, 65-66 and 70-71 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 6,371,988 (Pafford) in view of U.S. Pat. 4,349,921 (Kuntz).

The Applicants will address each basis for rejection in Sections I-III, respectively, which follow.

I. Anticipation over U.S. Pat. 5,728,159 (Stroever)

(Claims 59-61, 65-66 and 70-71)

Claims 59-61, 65-66 and 70-71 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 5,728,159 (Stroever). New claim 81 is dependent from claim 59. Claim 59 and its dependents are directed to "[a]n elongated bone implant . . . ." The dictionary definition of the term "elongated" means "long in proportion to width:Slender. [Exhibit D of the Second Response to the Official Action of 09/29/03: Webster's' Ninth New Collegiate Dictionary, Merriam-Webster Publishers, Springfield MA, 1988 at page 404.] According to the Patent Office, "the term 'elongate' used in the preamble . . .fails to breath life and meaning into the body of the claim and is given no patentable weight." [Official Action at page 3.] The Applicants respectfully disagree because the term "elongate" is a structural term and is not merely a statement of purpose as is the remaining recitation ("for use in spinal fusions") in the preamble. However, to eliminate this argument, the Applicants have amended the body of claim 59 to now recite dimensions associated with the term "elongated": "said elongated bone implant having a length of 20 mm to 26 mm, an overall width of approximately 7 mm to 12 mm and a height of between about 7.5 mm and 14.5 mm, said elongated bone implant comprising . . . ." Moreover, the term "elongated" is used in the body of claim and thus is entitled to weight in construing the Applicants' claim and distinguishing it from the "donut" shaped implants of Stroever which are cited by the Patent Office as prior art.

Separately, Stroever states that "The body portion 12 of each serrated bone graft section 10 has **a transverse cavity 13 (intermedullary canal) extending through body portion 12 between opposite end faces** 16." [Stroever at col. 3, lines 28-30; emphasis added in bold.] Consistent with this statement, Stroever shows in each of the implants of FIGS 1-7 the presence of the rough surfaced intramedullary canal 13. Applicants have added the limitation to claim 59 that "said elongated implant being free of an intermedullary canal as a transverse cavity through the body of said elongated implant." Support for this limitation is found in FIGS 8A-8G of the specification.

For all these reasons, Stroever is not anticipatory of claim 59 or any of its dependent claims (claims 61-62 and 65-69) or any of the method claims (claims 70-71) that recite the same implant structure as recited in claim 59. By simple analogy, the

crescent rolls or loafs of French bread of the Applicants' invention would not be anticipated by the donuts of Stroever.

(New Claims 82, 93, 105 and their dependents)

New independent claims 82, 93 and 105 would not be anticipated for the reasons described above and for an additional reason. As noted above, the implants of Stroever are "cross-sections" of fibula, tibia, humerus or femur. (Stroever at FIGS 8A-8C, and at col. 2, line 20 ("fibular cross-section bone grafts"); at col. 2, line 32 ("The serrated humeral cross-section bone grafts") and at col. 2, lines 45-46 ("The serrated tibial cross-section and serrated femoral cross-section bone grafts").]. As such, each of the cross-sectional implants of FIGS. 1-7 shows the naturally occurring medullary (aka "intermedullary") canal as a through-hole which runs from the top surface to the bottom surface of the resulting implants. [Stroever at col. 3, lines 26-27 ("The medullary canal . . .)] Moreover, Stroever states that each of his implants is characterized by the presence of the "intermedullary canal." [Stroever at col. 3 lines 28-30 ("The body portion 12 of **each** serrated bone graft section 10 **has** a transverse cavity 13 **(intermedullary canal) extending through body portion 12 between opposite end faces** 16."); emphasis added in bold.] In contrast, the implants claimed in the Applicants' invention are "elongated" and thus "free of a through hole comprising the intramedullary canal of the source bone and extending between said upper surface and said lower surface."

In addition, claims 82, 93 and 105 claim an implant having a combination of length (20-26 mm) and width (7-10 mm) that is neither taught nor suggested in Stroever. Moreover, the implants of Stroever are not elongate, but rather have a sufficiently uniform length and width as evidenced by Stroever's reference to them in terms of "diameter." Specifically, Stroever describes the "cross-sections" (col. 2, lines 20, 33 and 45) of his implants in terms of "diameter" because they have the natural shapes of the cross-sections of bone (fibula, humerus and femur) from which they are cut. Although Stroever uses the term "length," Stroever is referring to the length of the shaft of bone from which the implant is cut. [Stroever at col. 2, lines 20-27 ("The serrated fibular cross-section bone grafts shown in FIG. 1 can have exemplary **diameters** of about 10-14 mm and about 15-18 mm, with exemplary length of 8 mm, 10 mm, 12 mm and 14 mm. Additionally, elongate

shaft embodiments can have equivalent diameters, but exemplary **lengths** of 20 mm, 30 mm, 40 mm, 50 mm, 60 mm, 70 mm and **80 mm**.")]. Thus, in relation to the terms used in the Applicants' invention, the term "length," as used in Stroever, corresponds to "height" in the Applicants' invention. For these reasons also, the donut shaped implants of Stroever would not anticipate nor render obvious the elongated implants of the Applicants' invention, which lack an intermedullary canal.

Separately, claims 93 and 105 of the Applicants' invention recite "said first outer side wall comprises a convex surface and defines an outside angle of between about 60° and 75° with said posterior end, said second outer side wall comprises a concave surface." These limitations are neither taught nor suggested in Stroever. For this reason also, Stroever would not anticipate nor render obvious claims 93 or 105 or their dependents (claims 94-104).

Finally, claim 105 also recites that the elongated implant is "crescent shaped." See FIG. 8C. Stroever neither teaches nor suggests an implant that is crescent shaped. For this additional reason, Stroever would neither anticipate nor render obvious claim 105

For all these reasons, Stroever would neither anticipate nor render obvious claims 59-61, 65-66, 70-71 or 81-105.

II. Anticipation over U.S. Pat. 6,371,988 (Pafford)

(Claims 59-61, 65-66 and 70-71)

Claims 59-61, 65-66 and 70-71 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,371,988 (Pafford). According to the Patent Office, "referring to all figures [of Pafford] specifically figures 25 and 28, Pafford teaches a bone implant comprising a substantially planar upper and lower surfaces an anterior end and a posterior end, a first side wall and a second side wall opposite said first side wall, wherein the first and second side walls extend between the planar surfaces, and wherein the second side wall comprises a concave surface (right side of figure 25) and the first wall (left side in figure 25) comprises a convex surface." [Official Action at page 4.] The Patent Office then goes on to state that the implant of figure 25 "is elongate in one direction." [Official Action at page 4.] The Applicants respectfully submit that Pafford's

implant 50 of FIGS. 25 and 28 is the same cross-sectional implant disclosed in Stroever which contains the natural intramedullary canal. [Pafford at col. 10, lines 11-14 ("Such **cortical rings 50** are obtained by a **cross-sectional slice of the diaphysis of a long bone** and include superior surface 51 and inferior surface 52."); and at claim 15 ("A spinal spacer, comprising a load bearing member of cortical bone obtained from a **cross-sectional slice of the diaphysis of a long bone having a medullary canal**, said member having a wall, a superior surface and an inferior surface said wall sized for engagement within an intervertebral space and defining a chamber, said chamber including a portion of the canal, at least one of said surfaces defining surface roughenings for engaging the endplates of adjacent vertebrae."); emphasis added in bold. Generally, Pafford discloses that the preferred load bearing member in Pafford's implants contains the "intermedullary canal." [Pafford at col. 6, lines 46-48 ("A preferred load bearing member is obtained from the diaphysis of a long bone having a **medullary canal** which forms a **natural** chamber in the graft.")] Finally, the implants of Pafford, which are based upon Example 1 of Pafford, all contain the "intermedullary canals" of the diaphysis of a long bone. [See Pafford at Example 1 (entitled "Diaphysial Cortical Dowel"), col. 17, lines 6-9 ("The marrow was then removed from the medullary canal of the dowel and the cavity cleaned to create of chamber. The final machined product may be stored, frozen or freeze-dried and vacuum sealed for later use."). All of the implants of Pafford are based upon Example 1. In contrast to the implants of Pafford are based upon Example 1, claim 59 specifically recites "said elongated implant being free of an intermedullary canal as a transverse cavity through the body of said elongated implant." For this reason, claim 59 would neither be anticipated by nor obvious over Pafford. Because claim 59 would not be anticipated or obvious over Pafford, narrower claims 60-61, 65-66, 70-71 and 81, which depend from claim 59 and include the same limitation, would neither be anticipated by nor obvious over Pafford.

(New Claims 82, 93, 105 and their dependents)

Separately, Applicants have amended the body of independent claim 59 and also independent claims 82, 93 and 105 to recite dimensions associated with the term "elongated": "said elongated bone implant having a length of 20 mm to 26 mm, an overall

width of approximately 7 mm to 12 mm and a height of between about 7.5 mm and 14.5 mm." This limitation (or a narrower form thereof) is also incorporated into each dependent claim by reference thereto. However, this limitation is neither taught nor suggested in Pafford. For this reason, claims 59, 82, 93, 105 and their dependents would not be anticipated by or obvious over Pafford.

Separately, claims 93 and 105 of the Applicants' invention recite "said first outer side wall comprises a convex surface and defines an outside angle of between about 60° and 75° with said posterior end, said second outer side wall comprises a concave surface." These limitations are neither taught nor suggested in Pafford. For this reason also, Pafford would not anticipate nor render obvious claims 93 or 105 or their dependents (claims 94-104).

Finally, claim 105 also recites that the elongated implant is "crescent shaped." See FIG. 8C. Pafford neither teaches nor suggests an implant that is crescent shaped. For this additional reason, Pafford would neither anticipate nor render obvious claim 105

For all these reasons, Pafford would neither anticipate nor render obvious claims 59-61, 65-66, 70-71 or 81-105.

III. 35 U.S.C. § 103(a) Pafford over Kuntz

Claims 59-61, 65-66 and 70-71 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 6,371,988 (Pafford) in view of U.S. Pat. 4,349,921 (Kuntz). In its anticipation argument over Pafford and in the present argument, the Patent Office repeatedly cites to "all figures" in Pafford. [Official Action at page 5.] However, as pointed out previously, FIGS. 9, 10A, 10B, 11A, 11B, 12, 13, 14 15, 21, 22, 23, 34, 37 of Pafford are steel surgical instruments; FIGS. 53, 54, 55, and 59 of Pafford are bar graphs; and FIGS 57-58 of Pafford are mechanical testing devices. Thus, on their face, there is not even a remote argument that any one of the objects in these 20 figures could be anticipatory of an elongated bone implant. Accordingly, the Applicants will only respond to those contentions from the Patent Office for which specific arguments are made.

In a specific argument, the Patent Office contends that in figures 29-32, "Pafford et al teaches a bone implant comprising a substantially planar upper and lower

surfaces an anterior end and a posterior end, a first side wall and a second side wall opposite said first side wall, wherein the first and second side walls extend between the planar surfaces, and wherein the second side wall comprises a concave surface and the first wall comprises a convex surface." [Official Action at page 5.] The Patent Office further contends that the preambular term "elongate" fails to "breath life and meaning into the body of the claim." [Official Action at page 5.] The Applicants respectfully disagree.

The preambular term "elongate" is a structural term and is not merely a statement of purpose as is the remaining recitation ("for use in spinal fusions") in the preamble. However, to eliminate this argument, the Applicants have amended the body of claim 59 to now recite, "said first side wall and said second side wall being elongated relative to said anterior end and said posterior end." Accordingly, the body of claim 59 now includes a recitation of an elongated structure and orientation that is consistent with the preambular recitation of an "elongated" bone implant.

The Patent Office cites to the D-shaped implants of FIGS. 29-32 of Pafford and alleges that the Applicants are claiming half of Pafford's D-shaped implant. The Patent Office then cites to Kuntz for allegedly teaching that "a spinal implant can be formed in a singular configuration, as shown in figures 1-4, or in two halves, as shown in figures 5-6." [Official Action at page 5.] The Patent Office then concludes that it would have been obvious to one having ordinary skill in the art to have used the teachings of Kuntz forming a spinal implant in two halves with any vertebrae prosthesis including that of Pafford et al because "when a prosthesis for the lumbar area is required, it has been found advantageous to make the prosthesis in two halves. . ." [Official Action at page 5, citing to Kuntz at col. 9, lines 41 et seq.] The Applicants respectfully disagree.

The primary reference, Pafford, discloses implants that are characterized by the presence of the natural medullary canal that is present in the cross-sections of long bone that are used to make the implants of Pafford, including the D-shaped implants of FIGS. 29-32 therein. The secondary reference, Kuntz, discloses **solid** prostheses (implants) that lack a medullary canal. See Kuntz at FIGS. 1-11. Referring to Kuntz at col. 9, lines 41 et seq, which is relied upon by the Patent Office, Kuntz expressly teaches that the referenced 2 halves of the lumbar prosthesis in combination provide the same (solid) prosthesis as FIGS. 1 to 4:

> The prosthesis shown in FIGS. 1 to 4 is intended primarily as a cervical disc prosthesis. When a prosthesis for the lumbar area is required, it has been found advantageous to make the prosthesis in two halves, the division being in a longitudinal (posterior-anterior), vertical plane. Together, the two halves have a width equal to the total size of the space created when bilateral lumbar discectomy is carried out. **Apart from the two-part structure of the lumbar prosthesis, and a difference in overall dimensions, it is the same as the cervical prosthesis described in connection with FIGS. 1 to 4.**
>
> [Kuntz at col. 9, lines 41-52; emphasis added in bold.]

Thus, on its face, Kuntz discloses that but for their two part structure, the lumbar implants are "**the same**" as the **solid** implants of FIGS. 1 to 4. Referring to FIGS. 9 and 10 of Kuntz, these implant halves are shown as **solid** abutting halves that in combination make up a whole **solid** implant of FIGS. 1-4. There is no generic teaching or suggestion in Kuntz that the making of **solid** implants in halves is applicable to donut shaped implants having a large **hole** in the center, such as Pafford's implants having the natural medullary canal in the center. Kuntz also teaches that its implants have "slightly convex superior and inferior surfaces" [Kuntz at col. 6, lines 12-13] and that the reason for the convexity is to correspond to the concavity in the vertebrae and spread the load to "reduce the likelihood of damage to the cancellous vertebral bone structure":

> The **convexity** of the **superior** and **inferior** surfaces 11 and 12 **corresponds** closely to the **slight concavities found in the inferior and superior surfaces of the vertebrae** so that **loading** at the **vertebra/prosthesis interface** is **spread evenly**, resulting in reduced likelihood of damage to the cancellous vertebral bone structure.
>
> [Kuntz at col. 6, lines 21-27; emphasis added in bold.]

Thus, Kuntz teaches that a convexity on the superior and inferior surfaces of the implant, is needed to spread the load at the vertebrae/prosthesis interface. By doing so, Kuntz teaches away from having a hole in the middle of the implant which would fail to provide support and which would intensify (rather than spread) the load at vertebrae/prosthesis interface. Accordingly, when Kuntz is considered as a whole, there would be no motivation to select

Kuntz's teaching of making large lumbar implants from two halves while ignoring Kuntz's other teaching about having concave superior and inferior surfaces so that "loading at the vertebra/prosthesis interface is spread evenly." *See Bausch & Lomb, Inc. v. Barnes-Hind Int'l, Inc.*, 230 USPQ 416, 420 (Fed. Cir. 1986), *quoting In re Wesslau*, 147 USPQ 391, 393 (CCPA 1965) ("It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.").

For this reason, claims 59-61, 65-66 and 70-71 would not be unpatentable under 35 U.S.C. § 103(a) over U.S. Pat. 6,371,988 (Pafford) in view of U.S. Pat. 4,349,921 (Kuntz).

Moreover, the implants of Kuntz are not properly combinable with the implants of Pafford because the implants operate in different ways. The implants of Pafford are made from cross-sections of human cadaver bone and are naturally **porous**. They function by stimulating bone ingrowth and **fusing** the adjacent vertebrae:

> A need has remained for **fusion** spacers which **stimulate bone ingrowth** and **avoid the disadvantages of metal implants** yet provide sufficient strength to support the vertebral column until the **adjacent vertebrae are fused**.
>
> [Pafford at column 3, lines 55-58; emphasis added in bold.]
>
> * * *
>
> One benefit of the spacers of the present invention is that they combine the advantages of bone grafts with the advantages of **metals, without the corresponding disadvantages**. An additional advantage is that the invention provides a stable scaffold for **bone ingrowth** before **fusion** occurs.
>
> [Pafford at column 4, lines 13-17; emphasis added in bold.]

In contrast to Pafford, Kuntz discloses that its implant (prosthesis) is non-porous and does not have tissue ingrowth:

> The tissue does **not grow into** the structure of the prosthesis, **as would be the case if the surface were porous**, but **rather against the surface to encapsulate the prosthesis**.
>
> [Kuntz at col. 6, lines 42-45; emphasis added in bold.]

Kuntz expressly teaches against the use of "porous" materials such as the cortical bone used in Pafford:

> A major **disadvantage** of a **porous material** is that if there is **actual tissue ingrowth** into the prosthesis, **removal could be difficult**. Curetting out the prosthesis would lead to hemorrhage of a very vascular surface area, caused by the tissue ingrowth, with subsequent increased danger of cord compression secondary to hemorrhage.
>
> Besides, any **porous material** allowing tissue ingrowth for stability in a cervical spine **would be dangerous** as the esophagus, which lies anteriorly, could become adhered to the prosthesis with resultant dysphagia or difficulty in swallowing.
>
> There is consequently a **need** for a prosthesis that remains stably in place when implanted but **does not have the difficulties referred to above associated with porous surfaces**.
>
> [Kuntz at col. 2, lines 8-24; emphasis added in bold.]

As a result, Kuntz discloses that its prosthesis (implant) is composed of non-porous synthetic materials, such as "metal" (which Pafford teaches away from using):

> The prosthesis 10 is essentially a spacer and can be **fabricated from** any biologically acceptable material of suitable strength and durability, for example high density polyethylene, polymethylmethacrylate, **stainless steel**, or **chrome cobalt alloys**. The simplest material for fabrication of the prosthesis is a **polymer**, preferably high density polyethylene, and this may include a radiopaque marker so that the position of the prosthesis can be confirmed radiologically.
>
> [Kuntz at col. 7, lines 52-60; emphasis added in bold.]

Thus, the teachings of Pafford and Kuntz are not properly combinable because they teach away from one another and provide opposing solutions to the problem of treating compressed intervertebral discs. *See Monarch Knitting v. Sulzer*, 45 USPQ2d 1977, 1984

(Fed. Cir. 1998) ("A prior art reference may be considered to teach away when 'a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or **would be led in a direction divergent from the path taken by the applicant.**"); emphasis added in bold.

Separately, the implants of the Applicants' invention are inherently porous bone allografts that allow for ingrowth and **fusion**. [Specification at page 18, lines 27-28 ("In use, the implant 810 is inserted on either side of lumbar intervertebral spaces to thereby stabilize and assist in **fusion** of adjacent vertebrae."); emphasis added in bold.] However, as discussed above, Kuntz teaches away from the porous grafts of the Applicants' invention. *See Monarch Knitting v. Sulzer*, 45 USPQ2d 1977, 1984 (Fed. Cir. 1998) ("A prior art reference may be considered to teach away when 'a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or **would be led in a direction divergent from the path taken by the applicant.**"); emphasis added in bold. For this reason also, claims 59-61, 65-66 and 70-71 would not be unpatentable under 35 U.S.C. § 103(a) over U.S. Pat. 6,371,988 (Pafford) in view of U.S. Pat. 4,349,921 (Kuntz). *See In re Fine*, 5 USPQ2d 1596, 1599 (Fed. Cir. 1988) ("error to find obviousness where references 'diverge from and teach away from the invention at hand'"); *citing Gore v. Garlock*, 220 USPQ 303, 311 (Fed. Cir. 1983). Likewise, claims 72-80, which incorporate these same limitations and which are also free of intramedullary through holes, would not be obvious over Pafford in view of Kuntz.

Finally, each of independent claims 59, 82, 93 and 105 recites as a limitation "said elongated bone implant having a length of 20 mm to 26 mm, an overall width of approximately 7 mm to 12 mm and a height of between about 7.5 mm and 14.5 mm." This limitation is neither taught nor suggested in Pafford or Kuntz. For this reason, claims 59, 82, 93 and 105 and their dependents would not have been obvious over Pafford in view of Kuntz.

Separately, new claims 93 and 105 of the Applicants' invention recite "said first outer side wall comprises a convex surface and defines an outside angle of between about 60° and 75° with said posterior end, said second outer side wall comprises a concave surface." These limitations are neither taught nor suggested in Pafford or Kuntz, alone or

in combination. For this reason also, the combination of Pafford over Kuntz would not render obvious new claims 93 or 105 or their dependents (claims 94-104).

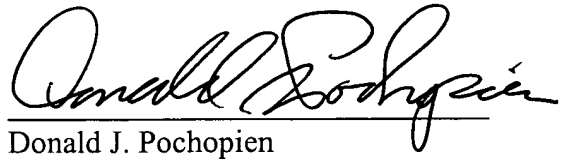
CONCLUSION

Pending claims 59-61, 65-66 and 70-71 are rejected. Claims 81-105 have been added by amendment herein. Accordingly, claims 59-61, 65-66, 70-71 and 81-105 are pending.

In view of the amendments herein, the rejection of claims 59-61, 65-66 and 70-71 for anticipation by either Stroever or Pafford has been rendered moot. In view of the arguments herein, the rejection of claims 59-61, 65-66 and 70-71 under 35 U.S.C. § 103(a) for allegedly being unpatentable over Pafford in view of Kuntz has been rebutted. For the reasons cited herein, new claims 81-105 would not be anticipated or obvious over the art cited by the Patent Office. Claims 59-61, 65-66, 70-71 and 81-105 are in condition for allowance. Their allowance is respectfully requested.

Respectfully submitted,

McANDREWS, HELD & MALLOY, LTD.

By: 

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Dated: May 05, 2005
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